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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,060	12/26/2007	Mark Parrington	API-03-13-PCT-US	8643
65626 7590 02/23/2010 PATRICK J. HALLORAN, PH.D., J.D. 3141 MUIRFIELD ROAD CENTER VALLEY, PA 18034			EXAMINER HAMA, JOANNE	
			ART UNIT 1632	PAPER NUMBER
			MAIL DATE 02/23/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/575,060	PARRINGTON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	JOANNE HAMA	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 38-47 is/are pending in the application.
- 4a) Of the above claim(s) 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-44, 46 and 47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant filed a response to the Non-Final Action of June 10, 2009 on December 10, 2009. Claims 1-37, 48-50 are cancelled. Claims 38, 39, 47 are amended. Claim 45 is withdrawn.

It is noted that Applicant must use the appropriate status identifiers for the claims or risk non-entry of the amendments. See 37 CFR 1.121. It is noted that claim 45 is withdrawn, as indicated in the Office Action of June 10, 2009, page 2.

Claims 38-44, 46, 47, drawn to an expression vector comprising a nucleic acid sequence of CAP(6D)-1,2 and human B7.1, are under consideration.

### ***Specification***

Applicant's arguments, see page 4 of Applicant's response, filed December 10, 2009, with respect to the objection to the specification have been fully considered and are persuasive. Applicant indicates that the sequence listing filed May 7, 2007 includes SEQ ID NOs. 11-14 and that specification has been amended to refer to SEQ ID NOs. 11-14 in the Brief Description of the Drawings. The objection of the specification has been withdrawn.

### **Withdrawn Rejection**

#### ***35 USC § 112, 2<sup>nd</sup> parag.***

Applicant's arguments, see page 4 of Applicant's response, filed December 10, 2009, with respect to the rejection of claims 38-44, 46, 47 have been fully considered

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and are persuasive. Applicant indicates that the phrase, "as illustrated in Figure 12," has been removed from the claims. The rejection of claims 38-44, 46, 47 has been withdrawn.

**Maintained Rejection**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 38-44, 46, 47 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Schlom et al., US Patent 6,045,802, in view of Matteucci, US Patent 4,923,808, patented May 8, 1990, Horig et al., 2000, Cancer Immunol. Immunother. 49: 504-514, Parmiani et al., 2002, J. Natl. Cancer Inst., 94: 805-818, for reasons of record, June 10, 2009.

Applicant's arguments filed December 10, 2009 have been fully considered but they are not persuasive.

Applicant disagree that all of the component parts are found in Schlom and Matteucci. The "parts" of the claimed subject matter include an expression vector, a nucleotide sequence encoding human CEA polypeptide, wherein the sequence contains 246 specific mutations to the "wild-type" CEA nucleotide sequence (e.g. Figure 9) and a nucleotide sequence encoding human B7.1. While certain expression vectors, wild type

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CEA and human B7.1 may be in the prior art, the rejection acknowledges that SEQ ID NO. 6 is not found in Schlom. Further, Matteucci do not disclose any CEA-encoding nucleotide sequences (Applicant's response, page 5). In response, this is not persuasive. With regard to Applicant indicating that Matteucci does not teach CEA-encoding nucleotide sequences, this was not the basis for combining Matteucci with Schlom. As indicated in the Office Action, June 10, 2009, pages 5-6, Matteucci was cited to teach that silent mutations were known at the time of filing that artisan used silent mutations to change the nucleotide sequence that encoded the protein, but that the nucleotide sequence did not change the sequence of the amino acid of the protein. Matteucci teaches that one advantage to making nucleic acid sequences with silent mutations is that some silent mutation nucleic acid sequences are better at translation (i.e. results in better protein production) than the wild type sequence. Given this teaching, an artisan would have taken the wild type nucleic acid sequence of CEA, made silent mutations, and identified nucleic acid sequences that resulted in higher expression of CEA protein. An artisan would have then taken the nucleic acid sequence with silent mutations that encodes CEA and used it in a vaccine expression vector. Higher expression of an antigen would provide a better chance for the immune system to mount a response against the epitope.

Thus, the claims remain rejected.

### ***Conclusion***

No claims allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Mondays, Tuesdays, Thursdays, and Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance.

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Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Joanne Hama/  
Primary Examiner  
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